Essex Cryogenics of Missouri, Inc.
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JUN 2 9 2012

510(k) Summary K 113767

1. Owner Information

Owner's Name:	Essex Cryogenics of Missouri, Inc.
Address:	8007 Chivvis Drive
	St. Louis, Missouri 63123-2395
Phone Number:	314-832-8077
Fax Number:	314-832-8208
Contact Person:	Kenneth L. Seise
Date:	December 16, 2011

2. Medical Device Information

Trade Name:	Mounted Medical Oxygen System (MMOS)
Common Name:	Portable Liquid Oxygen System
Classification Name:	Portable Liquid-Oxygen Unit

3. Substantial Equivalence to Predicate Medical Device

The MMOS is substantially equivalent to the Portable Therapeutic Liquid Oxygen System (NPTLOX) (K033000).

4. Medical Device Description

Physical and performance characteristics

The MMOS, when filled with liquid oxygen, is used to provide medical treatment to injured isolated personnel and to supplement environmental oxygen during high altitude and parachuting operations. The MMOS is primarily employed on board the HH-60, HC-130, and Guardian Angel (GA) rescue Vehicle to treat 1-2 patients for durations of 4-8 hours. The following general requirements apply.

a) The MMOS supplies 93% oxygen concentration when filled from an Oxygen Generator System (OGS).

b) The MMOS is capable of delivering gaseous oxygen to two patients at a combined maximum system flow rate of 22 Liters-Per-Minute (LPM) ambient.

c) The MMOS is capable of delivering oxygen at flow rate of 7 LPM for a minimum duration of 8 hours at one outlet.

d) The MMOS operating pressure is 50± 5 pounds per square inch gauge (psig).

e) The liquid oxygen (LOX) capacity is 4 liters.

f) The MMOS has two secondary accessory ports in addition to both patient ports.

g) The MMOS operates up to 14,000 Ft. MSL.

h) The oxygen delivery pressure is monitored and displayed.

i) The liquid oxygen quantity is monitored and displayed.

j) The MMOS has a visual low quantity alarm that triggers when the liquid capacity is at or below 10%.

k) Power required by the MMOS is a self-contained 9-volt lithium battery.

l) The MMOS has the capability to be filled with LOX by standard Department of Defense (DoD) and North Atlantic Treaty Organization (NATO) servicing connectors.

m) The overall system weight (when filled with 4.0 liters of liquid oxygen) is 35 lbs. Empty weight is 25 lbs.

n) The MMOS is 10.63 inches wide x 17.00 inches long x 8.75 inches wide within a tolerance of .06 inches in all directions.

How the device functions

The MMOS provides for storing of 4 liters of liquid oxygen and converting this liquid into its gaseous state. The gaseous oxygen is capable of being delivered in controlled amounts to provide medical treatment to injured patients and uncontrolled amounts to drive respiratory medical devices or supplemental oxygen in high altitude and parachuting operations. The MMOS is capable of being filled with liquid oxygen from the Oxygen Generator System (OGS) and with current liquid oxygen storage/ filling stations.

MMOS contains liquid oxygen (LOX). The MMOS contains a thermally insulated container of liquid oxygen (LOX) that is intended to supplement gases to be inhaled by a patient. The MMOS supports medical devices provided by the user including masks, cannulas, and Bag Valve Mask (BVM) being attached to the flow control patient outlets. An empty portable liquid oxygen unit is a device, while the oxygen contained therein is a drug.

The MMOS is portable. The handle on top of the housing, as well as the handles on the left and right side of the front-angled user interface, make the MMOS portable. The MMOS can be carried onboard, tied down, transported and operationally perform on various aircraft and ground vehicles.

The MMOS converts liquid oxygen from its insulated container through its heat exchanger into gaseous oxygen and finally the gaseous oxygen is available for distribution from an outlet port on the user interface. After connecting a tube assembly connector of a mask, cannula, and Bag Valve Mask (BVM) to an outlet port, masks, cannulas, and BVMs or other similar medical device (none of these devices is included in the MMOS) the patient can inhale the gaseous oxygen.

5. Intended Use of Medical Device

The MMOS is intended to convert liquid oxygen to gaseous oxygen for delivery to a patient and for delivery to rescue personnel to supplement environmental oxygen at high altitudes while mounted in rescue vehicles, e.g. HH-60 and HC-130 Guardian Angel (GA) rescue vehicles, at one-half (0.5) to fifteen (15) liters per minute (LPM) and fifty (50) pounds per square inch gauge (psig).

6. Comparison to Predicate Medical Device

The NPTLOX is the predicate medical device to which MMOS is compared. Both are portable. Personnel can move an NPTLOX device by picking up the unit by its two side handles and walking with it while personnel can move an MMOS device by picking up the unit by its two handles on the front-angled user interface or single top handle. Both the NPTLOX and MMOS devices are similar in that they include a thermally insulated container. Both containers are designed built, and tested per 49 CFR §178.57, Specification 4L welded insulated cylinders, and are housed in aluminum sheet metal enclosures that contain heat exchangers that convert the liquid oxygen to gaseous oxygen. Both devices have ports that can be connected to tubing intended for connection to an

oxygen mask or other similar medical device to ultimately supplement gases to be inhaled by a patient.

Both devices can be monitored for pressure and liquid oxygen quantity.

The differences in the NPTLOX and MMOS are in the container size and LOX capacity. The NPTLOX container is a sphere that is approximately 13.5 inches in diameter with a LOX capacity of 25 liters while the MMOS container is a cylinder that is approximately 11.3 inches long and 6.1 inches in diameter with a LOX capacity of 4 liters. Thus both the NPTLOX and MODS are portable liquid-oxygen units that function the same but are simply different sizes.

7. Medical Device Tests

Essex Cryogenics of Missouri, Inc. Engineering personnel completed extensive MMOS capability, performance, and environmental testing with no issues arising regarding its safety and efficiency. The combined testing and analysis of results provides assurance that the device meets it specifications and is safe and effective for its intended use.

8. Conclusions

Based on review of the design and test results, Essex Cryogenics of Missouri, Inc. believes that no significant differences exist between this medical device, MMOS, and the predicate medical device, NPTLOX, and therefore the MMOS as safe, as effective and performs as well as or better than the NPTLOX.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Essex Industries, Incorporated
Mr. Ken Seise
Quality Assurance Manager
Essex Cryogenics of Missouri, Incorporated
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Saint Louis, Missouri 63123

JUN 29 2012

Re: K113767
Trade/Device Name: Mounted Medical Oxygen System
Regulation Number: 21 CFR 686.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: June 14, 2012
Received: June 18, 2012

Dear Mr. Seise:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known):

Device Name: Mounted Medical Oxygen System

Indications for Use: The MMOS is intended to convert liquid oxygen to gaseous oxygen for delivery to a patient and for delivery to rescue personnel to supplement environmental oxygen at high altitudes while mounted in rescue vehicles, e.g. HH-60 and HC-130 Guardian Angel (GA) rescue vehicles, at one-half (0.5) to fifteen (15) liters per minute (LPM) and fifty (50) pounds per square inch gauge (psig).

Prescription Use____X____ AND/OR Over-The-Counter Use_____
(CFR Title 21, Part 801, Subpart D) (CFR Title 21, Part 801, Subpart C)

(PLEASE DON NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113767